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UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
SHERR-UNA BOOKER, an individual, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**PLAINTIFF'S RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 2 TO EXCLUDE IRRELEVANT AND PREJUDICIAL EVIDENCE REGARDING THE DEVELOPMENT OF THE RECOVERY FILTER** (The Honorable David G. Campbell) (Oral Argument Requested)

Plaintiff opposes Defendants' Motion and Memorandum in Support of Motion *in Limine* No. 2 to exclude relevant, probative evidence regarding development of the Recovery filter.

A. Evidence Regarding Development of the Recovery Is Highly Relevant.

The regulatory history of Bard's retrievable IVC filters demonstrates the relevance and admissibility of the development of its Recovery filter. *See* Exhibit A, Device History. The Recovery filter (K022236) was cleared for permanent use in November 2002 via the 510(k) process, which required it to be substantially equivalent in safety, technology and effectiveness to its predicate device, Bard's own Simon Nitinol Filter ("SNF").[1]

[1] In July 2003, the Recovery filter received clearance for an optional retrievable indication (K031328). *See* Exhibit B.

Bard submitted its next generation filter 510(k) for the "Recovery Filter System" on March 2, 2005 (K050558). Bard's FDA submission states "modifications to the Recovery Filter System are primarily dimensional and is [sic] a result of continued product improvement." Exhibit C, BPV-17-01-00125335, at 336 (emphasis added). The new "Recovery Filter System" (later renamed G2) was not a new or different device; it was merely an extension of the Recovery filter cleared in 2002 (K022236) and 2003 (K031328). Bard verified in a Truth and Accuracy Statement appended to its 510(k) application for the "Recovery Filter System" that this filter was substantially equivalent to the original Recovery filter. *Id*. at 389.[2] During the review process, Bard changed the name from "Recovery" to "G2"; however, neither the application nor information submitted for clearance were changed or altered. Exhibit D, BPV-17-01-00125616 at 620.

On August 29 2005, just 19 days after Bard renamed the Recovery filter "G2," the filter was cleared for permanent use via the 510(k) process. Bard used the Recovery (K022236) as the predicate – i.e., substantially equivalent in safety, technology and effectiveness, and in January 2008, the "Recovery G2" filter received clearance for an optional retrievable indication. Exhibit E, BPV-17-00125199, and Exhibit F. In its 510(k) submission seeking clearance to market the G2, Bard represented that the Recovery and G2 were fundamentally the same device, that the G2 was "identical to the Recovery Filter system (predicate) description and indications for use. The modifications made to the predicate filter and delivery system are primarily dimensional. No material changes or additional components have been incorporated." Exhibit G, FDA_PRODUCTION_ 00000048 (emphasis added).

This Court has recently determined, based on Georgia law, that evidence of Bard's compliance with federal regulations, specifically the 510(k) process, may be relevant. [Doc. 9881]. Under these circumstances, development of the Recovery and Bard's reliance on it as the "predicate device" for clearance of the G2 are central and relevant to

[2] This document was attached to the Declaration of Robert Carr in Support of Defendants' Motion for Summary Judgement Regarding Preemption as Exhibit 60 [Doc. 6396].

Plaintiff's claims. Further, one of the essential inquiries in determining whether a product is defectively designed is "'whether the design chosen was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware.'" *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 674 (Ga. 1994) (citations omitted). Evidence related to "tactical market decisions, product development and research/testing demands . . . can enter into a consideration of the reasonableness of a manufacturer's decision-making process." *Banks*, 450 S.E.2d at 675. Considering Bard's representations that the differences between the Recovery and G2 were "primarily dimensional" and not "material," the development of the G2's predicate device is highly relevant evidence to Plaintiff's causes of actions and should be admissible. Fed. R. Evid. 401, 403.[3]

B. Evidence Of The Recovery's Development Is Probative.

The scope of evidence Bard seeks to exclude related to "bad acts" is unclear from its Motion. Does Bard mean merely the three documents listed in its Motion, or all evidence related to the Recovery filter's development? The three listed documents are admissible.[4] If Bard is seeking to exclude any evidence of the Recovery filter's

[3] Contrary to Bard's contention, *Hockensmith v. Ford Motor Co.*, 2003 2003 WL 25639639 (N.D. Ga. April 17, 2003), is directly on point. There the court allowed evidence of design, development and testing of two other Ford vehicles on the ground that the design of the Ford at-issue "directly evolved from these earlier vehicles" and because two aspects of the alleged defects are "substantially similar." As discussed above, Plaintiff has shown the design defects at-issue with her G2 filter are substantially similar to the design aspects of the Recovery. *See* Pl.'s Opp. to Bard's Mot. *in Limine* No. 1.

[4] 1. The migration resistance comparative bench test demonstrated the Recovery filter: (a) performed worse than the SNF, (b) performed worse than almost all competitor devices, and (c) failed Bard's own performance threshold for resistance at 28 mm IVC. This test goes to the G2's defective and negligent design as it is predicated on and substantially equivalent to the Recovery. *See* Exhibit H, BPVE-01-00276094.

2. Testimony of Dr. Asch, Bard's consultant who managed the sole clinical study for the Recovery and permanent G2 filter (Plaintiff's filter). Filter complications during the study including fractures, migration, and perforation, caused the Canadian Institutional Review Board to suspend the study; however, Bard relied on this very study in seeking 510(k) clearance in the United States unbeknownst to Dr. Asch and against his advice. At the time Plaintiff's filter was cleared, this was the only clinical study Bard had conducted. *See* Exhibit I-1, Asch Dep.; Exhibit I-2, Asch Article, at 839-40, and Exhibit I-3.

development, as discussed above it would be unfair and misleading to exclude such evidence because the development and marketing of the Recovery and G2 occurred simultaneously. *See also* Exhibit K, Bard's July 2006 marketing strategy, "Recovery G2 Roadshow." Evidence of the history, development, marketing, and failures of the Recovery is relevant to a multitude of material issues in this case -- and is simply not the kind of "bad character" evidence courts exclude under Federal Rule of Evidence 404. But even if, *arguendo*, Bard is correct that some evidence of the development of the Recovery may be regarded as character evidence, the evidence is nonetheless admissible because it easily meets the bar for admissibility given the many issues besides "bad character" for which it is probative; it "may be admissible for another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident." Fed. R. Evid. 404(b)(2). Here, such information tends to show Bard knew of problems with its retrievable filter design, but ignored them. And instead of ceasing sale of the problematic filter while failures and flaws could be fully investigated and corrected, Bard made insignificant and immaterial design changes as part of a rebranding effort to escape the Recovery's negative branding. This evidence goes to Plaintiff's warning defect, design defect, negligence and punitive damages claims.

For the foregoing reasons, Defendants' Motion *in Limine* No. 2 should be denied.

RESPECTFULLY SUBMITTED this 8th day of February, 2018.

GALLAGHER & KENNEDY, P.A.

By: */s/ Mark S. O'Connor*
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3. Testimony of Kay Fuller, Bard's Regulatory Affairs Specialist handling the Recovery 510(k) application. Fuller did not sign the Truthfulness and Accuracy statement for the Recovery 510(k) because Bard had not adequately addressed the fracture failure mode. Carol Vierling, without permission, signed Fuller's name for her. *See* Exhibit J, Fuller Dep. Plaintiff will use this evidence for purposes other than "bad acts", such as to prove intent or knowledge, and for punitive damages. Fed. R. Evid. 404(b)(2).

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CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of February, 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti